

**Notice of Allowability**

Application No.

10/804,879

Applicant(s)

ABRIGNANI, SERGIO

Examiner

Zachariah Lucas

Art Unit

1648

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--**

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to the amendment of July 7, 2005, and the interview of August 12, 2005.
2. ☒ The allowed claim(s) is/are 18 and 24-27.
3. ☒ The drawings filed on 18 March 2004 are accepted by the Examiner.
4. ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) ☒ All    b) ☐ Some\*    c) ☐ None    of the:
    1. ☐ Certified copies of the priority documents have been received.
    2. ☒ Certified copies of the priority documents have been received in Application No. 09/011910.
    3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
  6. ☐ CORRECTED DRAWINGS ( as "replacement sheets") must be submitted.
    - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review ( PTO-948) attached
      - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date \_\_\_\_\_.
    - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

**Attachment(s)**

- |   |   |
|---|---|
| 1. <input type="checkbox"/> Notice of References Cited (PTO-892)  | 5. <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)                                 |
| 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                | 6. <input checked="" type="checkbox"/> Interview Summary (PTO-413),<br>Paper No./Mail Date <u>8/12/05</u> . |
| 3. <input type="checkbox"/> Information Disclosure Statements (PTO-1449 or PTO/SB/08),<br>Paper No./Mail Date _____ | 7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment   |
| 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit<br>of Biological Material          | 8. <input type="checkbox"/> Examiner's Statement of Reasons for Allowance                                   |
|   | 9. <input type="checkbox"/> Other _____   |

PD

### **DETAILED ACTION**

1. Currently, claims 18, and 24-27 are pending and allowed as amended in the After-Final amendment of July 11, 2005 and in the Examiner's Amendment below.

2. A Final rejection of claims 18, and 24-32 was mailed on April 7, 2005. On July 7, 2005, the Applicant submitted an After-Final amendment making changes to claims 18, 24-26, and 28-31. Upon review of the amendments, the Examiner called the Applicant to indicate that claims 18, and 24-27 would be in condition for allowance upon the amendment of claims 18, 25, and 26 as indicated below and in the attached interview summary.

During the course of the discussion, there were certain disagreements regarding the scope of claims 28-32 as amended in the submission of July 2005, and the Applicant agreed to their cancellation without prejudice to bring the other claims into condition for immediate allowance.

### **EXAMINER'S AMENDMENT**

3. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it **MUST** be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Michael J. Moran on August 12, 2005.

The application has been amended as follows:

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Claims 18 has been amended to insert the phrase - - from a human or chimpanzee cell, and - - between the terms “transmembrane protein” and “having” in line 5 (line 2 of subpart (a)) of the claim.

Claim 25 has been amended to cancel the phrase “that hyperexpresses said 24 kd protein” from line 2 of the claim.

Claim 26 has been amended to read as follows:

26. The method of claim 24, wherein the cell hyperexpresses said 24 kd protein, and is derived from a MOLT-4 cell.

Claims 28-32 have been cancelled from the application.

The amendment to claim 18 is made to overcome the rejection of this claim under 35 U.S.C. 112 first paragraph for lack of written description (the second basis of rejection provided under paragraph 9 of the Final action).

The amendment of claim 25 is made to clarify that the claim is drawn to the use of a protein produced by the MOLT-4 cell, not derivatives of this cell the hyperexpress the receptor.

The amendment of claim 26 to change it dependency from claim 25 to claim 24 is made to make the claim properly dependent. Claim 25 reads on embodiments wherein the cell is a MOLT-4 cell. Claim 26, which reads on the use of derivatives of such cells exceeds the scope of

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that claim, and therefore may not properly depend from it. Thus, claim 26 is amended to depend from claim 24.

The amendment of claim 26 to insert the indicated phrase is made to clarify that the derivative, not the parent MOLT-4 cell, is required to hyperexpress the protein.

Claims 28-32 are cancelled for the reasons indicated above, and in the attached interview summary.

***Claim Rejections - 35 USC § 112***

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. **(Prior Rejection- Withdrawn)** Claims 18 and 21-23 were rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted step is a method indicating how the ability to bind to the 24kd protein relates to the compounds ability to bind to HCV. In view of the amendment of the claim, the rejection is withdrawn.

6. **(Prior Rejection- Withdrawn)** Claims 28-32 were rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The rejection is withdrawn in view of the cancellation of the claims.

7. **(Prior Rejection- Withdrawn)** Claims 28-32 were rejected under 35 U.S.C. 112, second paragraph, as being indefinite as it is not clear what is meant by "the HCV receptor." In view of

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the amendments to the claim to clarify that the claims refer to the 24kd protein receptor for HCV, the rejection is withdrawn.

8. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

9. **(Prior Rejection- Withdrawn)** Claims 18 and 28 were rejected under 35 U.S.C. 112, first paragraph, because the specification, while being (for the purposes of this rejection) enabling for the claimed methods wherein the protein to which binding is being screened is the 24kd protein that binds to the HCV E2 protein, does not reasonably provide enablement for methods using any “functionally equivalent” or fragment thereof. In view of the amendment of claim 18 to read on the receptor actually identified in the application, or receptors of 24 kd that bind to E2 proteins from human or chimpanzee cells, and the cancellation of claim 28, the rejection is withdrawn.

10. **(Prior Rejection- Withdrawn)** Claims 18, 24-25, and 28-30 were rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The rejection is withdrawn in view of the amendments of the claims to read on the use of full length proteins of 24kd from human or chimpanzee cells that bind to the E2 proteins, the amendment of claim 26 to read on the cells that hyperexpress the MOLT-4 protein described in the application, and the cancellation of claims 28-30.

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11. **(Prior Rejection- Withdrawn)** Claims 18 and 24-27 were rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for methods of identifying compounds that bind to the 24 kd protein, does not reasonably provide enablement for methods of identifying compounds that compete with HCV for binding to any host cell receptor. In view of the amendments to the claims limiting them to compounds that bind to the 24 kd protein, the rejection is withdrawn.

12. **(Prior Rejection- Withdrawn)** Claims 28-32 rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. In view of the cancellation of these claims, the rejection is withdrawn.

### ***Conclusion***

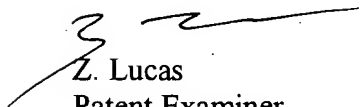
13. Claims 18 and 24-27 are allowed.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zachariah Lucas whose telephone number is 571-272-0905. The examiner can normally be reached on Monday-Friday, 8 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Z. Lucas  
Patent Examiner



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